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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Koichi SHUDO et al.

Confirmation No.: 5124

Application No.: 10/577,487

Group Art Unit: 1614

(U.S. National Phase of PCT/JP2004/016363)

Examiner: Not Yet Assigned

I.A. Filed : 10/28/2004

For : MEDICAMENT FOR THERAPEUTIC AND/OR PREVENTIVE  
TREATMENT OF RESTENOSIS OR REOCCLUSION AFTER  
VASCULAR RECANALIZATION OPERATION

**INFORMATION DISCLOSURE STATEMENT**

Commissioner of Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop **AMENDMENT**  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97, and 1.98, Applicants hereby bring the following information to the attention of the Examiner, which includes information cited and discussed in the specification, International Search Report, and the International Preliminary Report on Patentability. Copies of the International Search Report (in English and Japanese) and the International Preliminary Report on Patentability (in English) are also included herein.

Applicants note that the International Search Report and the International Preliminary Report on Patentability make reference to JP 2002-049632 (Institute of Medicinal Molecular Design, Inc.). However, it appears that this is an error and should be referring to WO 2002-049632.

The Examiner is invited to review the International Search Report and the International Preliminary Report on Patentability to inspect the relevance indicated during international examination with respect to the documents cited therein.

Accordingly, the Examiner is requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the attached Form-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office. If the Examiner needs additional copies of any of the documents, the Examiner is requested to contact the undersigned. For the Examiner's convenience, the documents are listed below.

Yamasaki, K., et al., "Inhibition of NF $\kappa$ B Activation Using cis-Element 'Decoy' of NF $\kappa$ B Binding Site Reduces Site Neointimal Formation in Porcine Balloon-Injured Coronary Artery Model," Gene Therapy, Vol. 10: 356-364 (2003); Applicants note that this document is cited and discussed at page 2, line 3, of the present application;

Yoshimura, S., et al., "Inhibition of Intimal Hyperplasia after Balloon Injury in Rat Carotid Artery Model Using cis-Element 'Decoy' of Nuclear factor- $\kappa$ B Binding Site as a Novel Molecular Strategy," Gene Therapy, Vol. 8: 1635-1642 (2001); Applicants note that this document is cited and discussed at page 2, line 4, of the present application;

Kozuma, K., "Drug Eluting Stent," Coronary Intervention, Vol. 1, No. 1: 58-62 (2002), accompanied by an English language translation thereof; Applicants

note that this document is cited and discussed at page 6, line 26, of the present application;

Hiatt, B., et al., "Drug Eluting Stents for the Prevention of Restenosis: In Quest for the Holy Grail," Catheterization and Cardiovascular Interventions, Vol. 55: 409-417 (2002); Applicants note that this document is cited and discussed at page 6, line 27, of the present application;

Curfman, G. D., "Sirolimus-Eluting Coronary Stents," New England Journal of Medicine, Vol. 346, No. 23: 1770-1771 (June 6, 2002); Applicants note that this document is cited and discussed at page 6, line 26, of the present application;

Morice, M., et al., "A Randomized Comparison of a Sirolimus-Eluting Stent with a Standard Stent for Coronary Revascularization," New England Journal of Medicine, Vol. 346, No. 23: 1773-1780 (June 6, 2002); Applicants note that this document is cited and discussed at page 6, line 28, of the present application;

WO 02/49632 A1, which was published on June 27, 2002, together with English language family member EP 1 352 650 A1 to Muto et al., which published on October 15, 2003; Applicants note that this document is cited and discussed in the specification, beginning at page 2, line 17;

WO 02/064065 A2, which was published on August 22, 2002; Applicants note that this document is cited and discussed at page 6, line 29, of the present application;

JP 2002-528420 A, which was published on September 3, 2002, together with English language family member WO 00/24412 A2, which published on May 4, 2000;

JP 2003-511110 A, which was published on March 25, 2003, together with English language family member WO 01/24866 A1, which was published on April 12, 2001.

Furthermore, Applicants direct the Examiner's attention to the following co-pending and commonly assigned U.S. patent application:

U.S. Patent Application Publication No. 2004/0259877 to MUTO et al., which was published on December 23, 2004, Applicants note that this document is the national stage of PCT/JP2001/11084 which has published as the aforementioned WO 02/49632 on June 27, 2002.

Copies of the above-noted documents, except for U.S. Patents and U.S. Patent Application Publications, are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicant respectfully requests that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

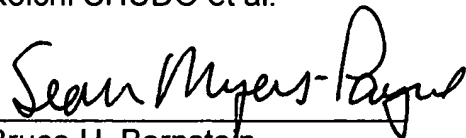
Further to 37 C.F.R § 1.98(a)(2)(ii) and to the U.S. Patent and Trademark Office's decision to waive the requirement under 37 C.F.R. § 1.98(a)(2)(iii), if a U.S. patent application was filed after June 30, 2003, copies of the U.S. patents and U.S. patent applications are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicant notes that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure

consideration of the submitted material. However, if an Office Action has issued, the U.S. Patent and Trademark Office is hereby authorized to charge any fee necessary for the consideration of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,  
Koichi SHUDO et al.



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FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P29865Application No.  
10/577,487INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT  
(Use several sheets if necessary)Applicant  
Koichi SHUDO et al.Filing Date  
I.A. Filed October 28, 2004Group  
1614

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2004 /	0 2 5 9 8 7 7	12/23/04	MUTO et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	0	2 / 4 9 6 3 2	06/27/02	W.I.P.O.			
		1 3 5 2 6 5 0	10/15/03	E.P.O.			
	02	/ 0 6 4 0 6 5	08/22/02	W.I.P.O.			
	2002	- 5 2 8 4 2 0	09/03/02	JAPAN			
	0	0 / 2 4 4 1 2	05/04/00	W.I.P.O.			
	2003	- 5 1 1 1 1 0	03/25/03	JAPAN			
	0	1 / 2 4 8 6 6	04/12/01	W.I.P.O.			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	Yamasaki, K., et al., "Inhibition of NFκB Activation Using cis-Element 'Decoy' of NFκB Binding Site Reduces Site Neointimal Formation in Porcine Balloon-Injured Coronary Artery Model," <u>Gene Therapy</u> , Vol. 10: 356-364 (2003).
2	Yoshimura, S., et al., "Inhibition of Intimal Hyperplasia after Balloon Injury in Rat Carotid Artery Model Using cis-Element 'Decoy' of Nuclear factor-κB Binding Site as a Novel Molecular Strategy," <u>Gene Therapy</u> , Vol. 8: 1635-1642 (2001).
3	Kozuma, K., "Drug Eluting Stent," <u>Coronary Intervention</u> , Vol. 1, No. 1: 58-62 (2002), accompanied by an English language translation thereof.
4	Hiatt, B., et al., "Drug Eluting Stents for the Prevention of Restenosis: In Quest for the Holy Grail," <u>Catheterization and Cardiovascular Interventions</u> , Vol. 55: 409-417 (2002).
5	Curfman, G. D., "Sirolimus-Eluting Coronary Stents," <u>New England Journal of Medicine</u> , Vol. 346, No. 23: 1770-1771 (June 6, 2002).
6	Morice, M., et al., "A Randomized Comparison of a Sirolimus-Eluting Stent with a Standard Stent for Coronary Revascularization," <u>New England Journal of Medicine</u> , Vol. 346, No. 23: 1773-1780 (June 6, 2002).

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.